REMARKS/ARGUMENTS

In response to the Final Office Action mailed October 28, 2010, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 6 is proposed to be amended, no new claims have been added and claims 9 and 10 were previously cancelled without prejudice so that Claims 6-8 remain pending. No new matter has been introduced.

Claims 6-7 were rejected as being unpatentable over U.S. Patent Publication No. 2005/0065596 to Tseng et al. (Tseng) in view of Windecker et al. (Current Pharmaceutical Design) and U.S. Patent Application Publication No. 2005/0106203 to Roorda et al. (Roorda). Claim 8 was rejected as being unpatentable over Tseng in view of Windecker and Roorda and further in view of U.S. Patent Publication No. US 2002/0013616 to Carter et al. (Carter). These rejections are respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations.

Tseng discloses trichostatin A. Windecker discloses the use of rapamycin. Roorda discloses the blends of polymers. Carter discloses stents. Focusing on Roorda, one can see that there are two inventions disclosed therein. One to an implantable medical device coated with a therapeutic agent and the other to an implantable medical device coated with a polymer or blend of polymers with the therapeutic agent contained therein. Roorda also specifically discloses the creation of a single layer of a blend of a fluoropolymer and an acrylate. This is not two single layers as claimed in the present invention.

Claim 6 claims a medical device comprising an implantable structure; a basecoat layer affixed to the implantable structure, the basecoat layer comprising a first polymeric material; trichostatin A, in thereapeutic dosages, releasably affixed to the implantable structure for the treatment of restenosis following vascular injury, the trichostatin A being incorporated into the basecoat layer, the concentration of trichostatin A being less than 100 nano molar; rapamycin, in therapeutic dosages, releasably affixed to the implantable structure for the treatment of restenosis following vascular injury, the rapamycin being incorporated into the basecoat layer, the rapamycin and the trichostatin A potentiating each others effectiveness; and a separate and distinct topcoat layer comprising a second polymeric material affixed to the basecoat layer to control the elution rate of the trichostatin A and the rapamycin, the topcoat layer comprising the second polymeric material and the basecoat layer comprising the first polymeric material being immiscible and chemically incompatible polymeric materials, wherein the first polymeric material includes a copolymer polyvinylidenefluoride-co-hexafluoropropylene and the

second polymeric material comprises poly(n-butylmethacrylate) layer, wherein the basecoat and the topcoat are affixed as separate and distinct layers upon each other and configured to create a chemical and physical barrier to elution of the rapamycin and the trichostatin A. None of the references, whether taken alone or in combination disclose or suggest the unique invention of amended independent claim 6. More specifically, the references ail to disclose or suggest all of the claimed elements in combination with distinct polymer layers to create physical and chemical barriers to drug elution. As indicated above, Roorda discloses blends as set forth in all his examples. In the present invention, the layers of polymers are distinct, there are no blends. As claim 8 depends from claim 6, the same arguments apply. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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